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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,609	01/24/2002	David F. Karnosky	16313-0093	2922

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EXAMINER
KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,609	KARNOSKY ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/02, 3/03*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 19 August 2002 and 31 March 2003 have been considered, signed copies are attached hereto.

Drawings

2. The Drawings filed 7 May 2002 are acceptable to the Examiner.

Specification

3. The use of the trademarks AUGMENTIN™ on pages 17 and 18, and CHLOROX™ on page 18 has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Objections

4. Claims 2, 9, 10, 13 and 22 objected to because of the following informalities:

At claims 2, 13 and 22, the recitation "a Larix genus" and "a Populus genus" are nonsensical because "Larix" and "Populus" are genera of trees, it appears that Applicant means selected from a Larix species or a Populus species at claims 2 and 22. Deleting "a" and "genus" in claim 13 in the list of species would obviate this rejection.

At claims 9 and 10, line 1, the phrase "a tree cell" should read -- the tree cell -- in referring to claims 1-8.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 7, 8, 18, 19, 27 and 28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 7, 18 and 27, line 2, the phrase "a polynucleotide as shown in SEQ ID NO: 2" renders the claim indefinite because it is unclear if this limitation is mean to encompass fragments of SEQ ID NO: 2, hence the metes and bounds of the claimed invention are unclear.

At claims 8, 19 and 28, line 2, the phrase "a polypeptide as shown in SEQ ID NO: 3" renders the claim indefinite because it is unclear if this limitation is mean to encompass fragments of SEQ ID NO: 3, hence the metes and bounds of the claimed invention are unclear.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 5-12 and 16-29 rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a *Larix* or *Populus* tree comprising a transgene encoding an altered AHAS enzyme that increases resistance to an imidazolinone herbicide, a method of making said *Larix* or *Populus* tree and a method of using a *Larix* or *Populus* tree comprising a transgene encoding an altered AHAS

enzyme that increases resistance to an imidazolinone herbicide, does not reasonably provide enablement for any transgenic tree or tree cell transformed with an altered AHAS nucleic acid that results in increased resistance to an imidazolinone herbicide or a method of making any such transgenic tree or tree cell, in addition, the specification does not reasonably provide enablement for trees comprising an altered AHAS nucleic acid wherein said tree is non-transgenic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant only teaches how to make and use a *Larix* or *Populus* tree comprising a transgene encoding an altered AHAS enzyme that increases resistance to an imidazolinone herbicide.

Applicant does not teach how to make and use other transgenic trees within the full scope of the claimed invention. In addition, Applicant does not teach how to make and use trees comprising an altered AHAS nucleic acid wherein said tree is not transformed to comprise a transgene encoding an altered AHAS enzyme.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for how to make and use transgenic trees within the full scope of the claimed invention. The art teaches that plant transformation remains an art because of the unique culture conditions required for each species (Hansen and Wright 1999, Trends in Plant Science 4(6): 226-231, see page 230, right column). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use any transgenic tree or tree cell transformed with an altered AHAS nucleic acid that results in increased resistance to an imidazolinone herbicide as broadly claimed.

At claims 21-25, Applicant provides no guidance on how to make and use a tree comprising an altered AHAS nucleic acid wherein said tree has not been transformed with a transgene.

At claims 6, 17 and 26, part "e)", "a polynucleotide complementary to" is not enabled because SEQ ID NOs: 1-3 represent *Arabidopsis thaliana* a nucleotide or amino acid sequence, and Applicant provides no guidance for expressing an antisense construct for an *Arabidopsis thaliana* protein or nucleotide sequence in a tree, in addition, the antisense would not produce a tree having increased resistance to an imidazolinone herbicide as claimed. In addition, at part "d)", a polynucleotide comprising only 60 consecutive nucleotides would only encode a 20 amino acid polypeptide, such a polypeptide has not been show by Applicant to produce imidazolinone herbicide resistance in a transformed tree comprising said polynucleotide, hence this limitation is not enabled.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 2, 4-13, 15-22 and 24-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tsai *et al* (1994, Plant Cell Reports 14: 94-97) in view of Sathasivan *et al* (U. S. Patent 5,767,366, published 16 June 1998).

Tsai *et al* teaches a method of transforming *Populus tremuloides* and regenerated trees with an expression cassette comprising a transgene encoding NPT II selection marker gene operably lined to a transcription initiation regulatory region and a translation initiation regulatory region that function in a tree (page 95, left column, 7th paragraph). Tsai *et al* also teach regenerated transgenic trees (see page 96, left column).

Tsai *et al* do not teach transforming *Populus tremuloides* with a nucleic acid encoding an altered AHAS nucleic acid, specifically having the nucleic acid sequence shown in Applicant's SEQ ID NO; 1 or 2, or encoding the polypeptide as shown in Applicant's SEQ ID NO: 3.

Sathasivan *et al* teach an isolated nucleic acid having the nucleic acid sequined of Applicant's SEQ ID NO: 1 or 2 and encoding the polypeptide as shown in Applicant's SEQ ID NO: 3 (see the sequence listing below column 16).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Tsai *et al* to substitute the NPT II selection marker gene for the modified AHAS encoding nucleic acid taught by Sathasivan *et al*. Tsai *et al* motivates one of ordinary skill in the art to transform *Populus* trees to comprise agronomically useful genes, which confer tolerance to herbicides (see page 94, right column 1st paragraph). Sathasivan *et al* also motivates one of ordinary skill in the art to use the taught altered AHAS nucleic acid to make transformed plant to confer resistance to imidazolinones (see column 3, 3rd paragraph). Given the success of Tsai *et al* in producing transformed *Populus* trees, one of ordinary skill in the art would have had a reasonable expectation of success in making a transgenic tree transformed by an altered AHAS nucleic acid as claimed by Applicant.

11. Claims 3, 14 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shin *et al* (1994, Can. J. For. Res. 24: 2059-2067) in view of Sathasivan *et al* (U. S. Patent 5,767,366, published 16 June 1998).

Shin *et al* teach of method of transforming Larix trees to comprise gene encoding for herbicide resistance (see page 2060, left column). Shin *et al* also teach transformed Larix trees (see page 2060, right column). Shin *et al* teach transforming a Larix trees with an expression cassette comprising a transgene encoding an *aroA* herbicide resistance gene operably lined to a transcription initiation regulatory region and a translation initiation regulatory region that function in a tree (see page 2061).

Shin *et al* do not teach transforming a Larix tree with a nucleic acid encoding an altered AHAS nucleic acid, specifically having the nucleic acid sequence shown in

Applicant's SEQ ID NO; 1 or 2, or encoding the polypeptide as shown in Applicant's SEQ ID NO: 3.

Sathasivan *et al* teach an isolated nucleic acid having the nucleic acid sequined of Applicant's SEQ ID NO: 1 or 2 and encoding the polypeptide as shown in Applicant's SEQ ID NO: 3 (see the sequence listing below column 16).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Shin *et al* to substitute the *aroA* herbicide resistance gene with the altered AHAS nucleic acid taught by Sathasivan *et al*. Shin *et al* motivates one of ordinary skill in the art to transform Larix trees with herbicide resistance genes because Larix trees are "notoriously susceptible to herbicides" (see page 2060, left column, 2nd paragraph). Sathasivan *et al* also motivates one of ordinary skill in the art to use the taught altered AHAS nucleic acid to make transformed plant to confer resistance to imidazolinones (see column 3, 3rd paragraph). Given the success of Shin *et al* in producing transformed Larix trees, one of ordinary skill in the art would have had a reasonable expectation of success in making a transgenic tree transformed by an altered AHAS nucleic acid as claimed by Applicant.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
25 August 2003